In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-1152V

ALISON STIEGLER, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: October 10, 2024

Andrew Downing, Downing, Allison, & Jorgenson, Phoenix, Arizona, for Petitioner.

Sarah Duncan, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION DENYING ENTITLEMENT[1]

On April 2, 2021, Alison Stiegler filed a Petition under the National Vaccine Injury Compensation Program (the "Vaccine Program"),[2] alleging that she developed Postural Orthostatic Tachycardia Syndrome ("POTS") and chronic fatigue syndrome ("CFS") as a result of receiving the tetanus, diphtheria, and acellular pertussis ("Tdap") vaccine on April 4, 2018. ECF No. 1 ("Petition").

[1] This Decision will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published Ruling's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire Decision will be available to the public in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012)) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

On October 2, 2023, I held a status conference, after which I ordered Petitioner to file a brief explaining the theory offered in this case. ECF No. 68. On January 19, 2024, Petitioner filed that brief. ECF No. 69 ("Brief"). Two months later, on March 25, 2024, I issued another order reiterating the preliminary view (based on my experience adjudicating POTS claims) that the Petition was not tenable, and expressing my willingness to entertain dismissal. ECF No. 72.

Respondent has now formally moved to dismiss the claim, and both sides have had an opportunity to weigh in on the matter. *See* Respondent's Rule 4(c) Report (ECF No. 73) and associated Motion to Dismiss, filed April 30, 2024 (ECF No. 74) (collectively, "Mot."); Petitioner's Response, filed July 2, 2024 (ECF No. 81) ("Opp."); Petitioner's Motion for Oral Argument, filed July 8, 2024 (ECF No. 82); Respondent's Reply, filed July 15, 2024 (ECF No. 83) ("Reply"); Respondent's Response to Motion for Oral Argument, filed July 18, 2024 (ECF No. 84); Petitioner Reply in Support of Motion for Oral Argument, filed July 24, 2024 (ECF No. 85).

Having reviewed the record and all associated filings, I hereby deny an entitlement award. Although this case involves the Tdap vaccine, Petitioner relies heavily on the contention that the human papillomavirus vaccine ("HPV") can cause POTS. But claims involving an alleged HPV/POTS association have been routinely rejected in numerous prior Program cases as lacking reliable scientific support sufficient to meet the preponderant burden of proof. Otherwise, Petitioner offers minimal, unpersuasive evidence specific to a purported Tdap/POTS association, and does not advance sufficient basis to entertain further a CFS claim based on the same facts.

I. Factual Background

Pre-Vaccination History

In the three years prior to her vaccination, Ms. Stiegler saw medical providers for multiple symptoms that continued after she received the Tdap vaccine. Thus, in October 2015, she presented to the emergency room ("ER") complaining of shortness of breath with diffuse chest tightness and increased stress at work, and was diagnosed with a panic attack, given Ativan, and prescribed albuterol for wheezing. Ex. 13 at 12, 15. In December 2015, Petitioner presented to the ER and reported she had been experiencing almost daily abdominal discomfort or pain since April 2015, and reported that at times it went up to her chest and shoulders and was accompanied by shortness of breath. *Id.* at 56-59. She was diagnosed with gastritis versus gastroesophageal reflux disease with an anxiety component. *Id.*

Vaccination and Subsequent Manifestations of Symptoms

On April 4, 2018, Petitioner received the Tdap vaccine after stepping on a nail three days earlier. Ex. 13 at 140-41, 150, 153. At the appointment, she complained of mild, intermittent headaches for the past month, fever, chills and stomach pain. *Id.* at 140-41. She also complained of pain after injuring her knee doing jujitsu the day before. *Id.* She was diagnosed with a likely tension headache, likely flu infection, a puncture wound, and a knee sprain or meniscal injury. *Id.* at 142.

Over the next several months, Petitioner continued to report to her primary care physician ("PCP") complaining of chronic headaches and pain in her knee, ankle, and hand from jujitsu. Ex. 6 at 7-8, 17, 49, 59-61. In August 2018 (four months post-vaccination), Petitioner presented to her PCP complaining of sciatic back pain that had worsened the day before, adding that she had been experiencing comparable symptoms for several years. Ex. 6 at 66.

On October 31, 2018, more than six months post-vaccination, Petitioner saw her PCP and reported three weeks of unusual fatigue. Ex. 6 at 108. Her exam was normal, but during the appointment, she began sobbing and reported that she continuously checked her phone, calendar, and tasks, thinking something was wrong or would happen. *Id.* at 110. She reported that she had not slept well for a while because she would think about needing to wake up and urinate, which prevented her from sleeping, and that her periods were becoming irregular. *Id.* The differential diagnoses included likely obsessive-compulsive disorder with anticipatory anxiety, vitamin deficiency, endocrine issue, and psychosomatic complaints. *Id.* Thus, by this date, Petitioner was not reporting symptoms that might reflect POTS.

Treatment in 2020 and Beyond

Throughout 2019, Petitioner went to the ER three times for matters unrelated to the present case. Ex. 7 at 2-3; Ex. 30 at 7, 11. During her third visit on September 15, 2019, Petitioner complained of back pain, chest pain/pressure and shortness of breath for two weeks. Ex. 5 at 37. She also reported that she had experienced palpitations while watching TV that night. *Id.* at 89. She was diagnosed with nonspecific chest pain, lumbosacral strain, and left shin pain. *Id.* at 95. In the following year, she had additional ER visits, where she complained of shortness of breath, hyperventilation, and chest pain/tightness. Ex. 5 at 122-25, 174, 176, 198.

On April 27, 2020, Petitioner had a telehealth visit with a gastroenterologist ("GI doctor"). Ex. 19 at 2. She reported that that she recently had difficulty breathing and explained that she never had this issue before. *Id.* She also complained of five years of bloating, which she controlled by avoiding certain foods. *Id.* The GI doctor diagnosed her with mixed irritable bowel syndrome ("IBS") and advised her to follow up with her PCP and OB-GYN regarding her other symptoms.

Id. at 3-4. On April 30, 2020, Petitioner had a follow-up appointment with her GI doctor, who noted that her only finding after multiple ER and clinical visits was gallstones. *Id.* at 6-8. Petitioner became extremely upset during this appointment, and the GI doctor recommended she go to the ER where the doctor's colleagues could evaluate her. *Id.* The surgical consult at the hospital recommended that Petitioner have her gallbladder removed but Petitioner declined. Ex. 4 at 14-15. Thus, as of *two years* post-vaccination, Petitioner had not reported the kinds of symptoms that would be classically reflective of POTS, but instead constituted a variety of nonspecific complaints. *See,* e.g., Ex. 19 at 18, 21.

On June 12, 2020, Petitioner presented to a chiropractor because she was "feeling 'out of whack,'" wanted "a neurological assessment to address any areas of imbalance," "suspect[ed] autoimmunity," and was having numbness, tingling, and headaches. Ex. 27 at 11. She saw the chiropractor six more times through July 8, 2020. *Id.* at 5-10. On June 19, 2020, a week later, Petitioner presented to a new PCP for an annual exam and reported that she was feeling well and had no specific complaints. Ex. 25 at 2. Nevertheless, Petitioner sought treatment from a variety of other specialists through that summer, reporting concerns or asking about potential diagnoses that could not be confirmed. *See generally* Ex. 9 at 2; Ex. 10 at 7; Ex. 22 at 7; Ex. 25 at 3, 23; Ex. 8 at 13; Ex. 29 at 51. These efforts continued into the fall, and some treaters eventually proposed that the subjective and unsubstantiated nature of Petitioner's complaints could reflect a psychologic rather than physical issue. Ex. 8 at 3-5, 31, 85.

The closest Petitioner has come to a POTS diagnosis occurred in the context of a cardiologic visit in March 2021 (now *three* years post-vaccination). Ex. 16 at 8. She reported to the treater that when she stood or lied down, she had intermittent episodes where her heart raced, her symptoms would thereafter last a few seconds to hours, were sometimes associated with shortness of breath, and that these episodes began the year before. *Id.* at 8, 9. Petitioner felt that she might have POTS and was very flexible, might be double jointed, and have Ehlers-Danlos syndromes. *Id.* On exam, Petitioner had a heart murmur, but no cyanosis and her joints were normal. *Id.* at 9. The cardiologist diagnosed her with palpitations, chest discomfort, a heart murmur, abnormal EKG, shortness of breath, likely hypermobility syndrome, and shortness of breath. *Id.* at 6, 9.

Petitioner thereafter continued to seek medical assistance for many different complaints and symptoms. In her affidavit, Petitioner reported a myriad of symptoms (unrelated to her CF and POTS claims) that she attributes to the Tdap vaccine, including chemical smell sensitivity, loss of height, low blood pressure, becoming a magnet for animals, an allergic reaction to sandflies, and fibrocystic breast disease. Ex. 1 at 6, 7.

II. Procedural History

As noted above, the case was initiated in April 2021. On October 2, 2023, I held a status conference and explained my reasons for doubting Petitioner's theory that POTS is predominantly autoimmune and can be caused by certain vaccines. I acknowledged, however, that I had yet to adjudicate a case in which Petitioner alleges that the Tdap vaccine specifically caused POTS, and I found it conceivable that a causation theory involving the Tdap vaccine could be different from other claims. I thus ordered Petitioner to file a brief explaining the theory offered in this case. After Petitioner did so, Respondent filed a Rule 4(c) Report and moved to dismiss the claim. In the course of briefing the topic, Petitioner also briefed the propriety of oral argument. No expert reports have been filed, and the motion to dismiss is now ripe for resolution.

III. Parties' Arguments

Petitioner[3]

Petitioner argues that POTS is an autoimmune disease that can be triggered by the Tdap vaccine via molecular mimicry. Brief at 5, 20.[4] She contends that recent research supports the conclusion that autoimmunity is a widely-accepted cause of POTS, rendering the Program's previous conclusion – that POTS is not autoimmune – outdated. *Id.* at 1. And, she maintains, patients with POTS often report an immunological trigger (like vaccination) prior to their onset of symptoms, which is a feature of autoimmune disease. *Id.* at 2; Opp. at 38.

In support, Petitioner cites several items of literature – although most were submitted in other cases alleging POTS as a vaccine injury, but deemed unreliable or unpersuasive.[5] Brief at 2-4, 8-9; Opp. at 40-41. In particular, she cites several articles that discuss a purported connection between POTS and the HPV vaccine. Brief at 5-7 (citing[6] S. Blitshteyn, *Postural Tachycardia Syndrome Following Human Papillomavirus Vaccination*, 21 European J. of Neurology 135 (2014) (filed as pages 103-07 of ECF No. 71) ("Blitshteyn"); R. Chandler et al., *Current Safety Concerns with Human Papillomavirus Vaccine: A Cluster of Reports in VigiBase*, 40 Drug Saf.

[3] My summary of Petitioner's arguments draws from both Petitioner's initial filing in response to my concerns about the claim's viability, as well as her later brief opposing Respondent's dismissal motion.

[4] Although, as noted above, Petitioner has also alleged CFS as an injury in this case, her briefing has little to say about it. She simply references the same molecular mimicry theory, claiming that impairment of certain adrenergic receptors allegedly implicated in an autoimmune form of POTS can lead to symptoms of CFS. Opp. at 53.

[5] For a review of these papers and articles, *see generally A.F. v. Sec'y of Health & Hum. Servs.*, No. 19-446V, 2023 WL 251948, at *7, *15 n. 22, *23 (Fed. Cl. Spec. Mstr. Jan. 18, 2023).

[6] Petitioner did not properly file the 39 articles cited in her Brief as separate and individual exhibits, but instead simply included them in an appendix. ECF No. 71. I will therefore reference the page numbers of the relevant submission in citing to these items of literature.

81 (2017) (filed as pages 133-42 of ECF No. 71) ("Chandler"); J. Schofield & J. Hendrickson, *Autoimmunity, Autonomic Neuropathy, and the HPV Vaccination: A Vulnerable Subpopulation*, Clin. Ped. 1 (2018) (filed as pages 119-122 of ECF No. 71) ("Schofield"); L. Brinth et al., *Orthostatic Intolerance and Postural Tachycardia Syndrome as Suspected Adverse Effects of Vaccination Against Human Papilloma Virus*, 33 Vaccine 2602 (2015) (filed as pages 81-84 of ECF No. 71) ("Brinth")). But these articles also have been considered in prior cases, and thus do not represent new or updated "takes" on the alleged POTS-HPV vaccine association that render a causal relationship more likely. *See, e.g., C.F. v. Sec'y of Health & Hum. Servs.*, No. 15-731V, 2023 WL 2198809 at *15, *17-19, *32 (Fed. Cl. Spec. Mstr. Jan. 20, 2023).

Petitioner also maintains other vaccines could be causal of POTS, even if the HPV vaccine remains the most common and likely trigger. For example, several case studies have reported patients developing POTS within weeks of receiving the COVID vaccine. Brief at 5 (citing P. TV et al., *Postural Orthostatic Tachycardia Syndrome-like Symptoms Following COVID-19 Vaccination: An Overview of Clinical Literature*, 31 Hum Antibodies, 9-17 (2023) (filed as pages 69-77 of ECF No. 71) ("TV et al."); Opp. at 38 (citing C. Pena et al., *Autoimmunity in Syndromes of Orthostatic Intolerance: An Updated Review*, 14 J. Pers. Med., 2 (2024), filed as Ex. 37 (ECF No. 79)). But the COVID vaccine is not at issue herein (nor could it be, as it is not at present a Program-covered vaccine).

Turning to the alleged relationship between the Tdap vaccine and POTS/CFS, Petitioner claims that the tetanus wild bacterium has been frequently connected to autonomic dysfunction. Brief at 17 (citing Won Seo et al., *Autonomic Instability in Severe Tetanus: A Case Report*; 23 Ann. Clin. Neurophysiology 117-120 (2021) (filed as pages 394-97 of ECF No. 71) ("Won Seo") (individual patient case report). Petitioner thus assumes that the impact of the Tdap vaccine's tetanus *toxoid* component (which is understood not to be equivalent to a wild tetanus infection, and thus inherently less dangerous) can also cause autonomic dysfunction.

To prove that the Tdap vaccine can cause POTS (or CFS for that matter), Petitioner points to the mechanism of molecular mimicry, in which the body produces autoantibodies in response to a vaccine's antigens that then (due to similarity between the antigens and self-tissue structures or components) erroneously cross-react, attacking the body. Brief at 9; Opp. at 47. Interference with the Alpha-1 adrenergic receptor (found on the surface of sympathetic nerve cells) is suspected to be causative of POTS. Opp. at 47. Antibodies generated in response to the Tdap vaccine bind to these receptors, due to sequence homology between Tdap vaccine peptide components and those found in the adrenergic receptors. *Id.* at 54. To prove this, Petitioner's counsel conducted a UnitProt analysis between tetanus toxoid and the human antigen target of the Alpha-1 adrenergic receptor. *Id.* The results of the analysis revealed that there are nine homologous amino acids in the

run of twelve, and seven in a linear match. *Id*. at 57. This homology, Petitioner argues, is sufficient to support the theory that Petitioner developed POTS via molecular mimicry. *Id.*[7]

As independent support for this causal theory, Petitioner referenced several items of literature. Opp. at 50-51 (*citing* A. Fedorowski et al., *Antiadrenergic Autoimmunity in Postural Tachycardia Syndrome*, 19 Europace 1211 (2017) (filed as pages 268-76 of ECF No. 71); H. Li et al., *Autoimmune Basis for Postural Tachycardia Syndrome*, 3 J. Am. Heart. Ass'n. 2 (2014) (filed as pages 257-66 of ECF No. 71); W. Gunning et al., *Postural Orthostatic Tachycardia Syndrome is Associated with Elevated G-Protein Coupled Receptor Autoantibodies*, 8 J. Am. Heart Assoc. 1–10 (2019)) (filed as pages 311-320 of ECF No. 71)). But I have reviewed all these articles in previous cases and found them to be unpersuasive. *A.F. v. Sec'y of Health & Hum. Servs.*, No. 19-446V, 2023 WL 251948 at *5, *24 (Fed. Cl. Spec. Mstr. Jan. 18, 2023).

Respondent

At the outset, Respondent disputes that Petitioner ever suffered from either POTS or CFS. Mot. at 26. Petitioner never received *either* diagnosis from a treater, nor has she undergone testing sufficient to meet the diagnostic criteria for these conditions. *Id.* At most, Petitioner expressed concern that she *might* have POTS in March 2021, but her cardiologist did not diagnose her with the condition or order further testing. *Id.* And when Petitioner reported fatigue to various providers, she reported only brief periods of fatigue at sporadic times, and thus her complaints in this regard were too nonspecific to amount to the conclusion she actually had CFS. *Id.* at 27.

Moreover, Respondent argues, even if Petitioner could show that she suffered from POTS and/or CFS, Petitioner cannot establish causation. Mot. at 27. In particular, Petitioner has failed to provide convincing evidence that POTS has an autoimmune basis. *Id.* at 30.

Respondent observes that most of Petitioner's cited literature has already been evaluated and rejected in previous Vaccine Program cases. Mot. at 28. And any new medical literature offered by Petitioner does not constitute preponderant evidence that POTS is an autoimmune condition. *Id.* at 30. One such article, for example, merely suggests that patients with POTS can also suffer from antiphospholipid syndrome,[8] which Petitioner does not have. *Id.* (discussing H.A. Noureldine et al., *Postural Tachycardia Syndrome (POTS) and Antiphospholipid Syndrome (APS): What Do We Know So Far?*, 178 Rev Neurol (Paris) 306-314 (2022) (filed as pages 38-41 of ECF No. 71)). Another only suggests a possible genetic/inherited character for POTS, as opposed to it

[7] Although in most cases an expert in immunology and/or molecular biology would be called for to perform this homology analysis, counsel attempts to do so here – but given the posture of the case, I do not fault the effort (even if I ultimately do not find that it aided Petitioner's claim in the least).

[8] "Antiphospholipid syndrome" is defined as "a multisystem inflammatory disorder characterized by the presence of circulating antiphospholipid antibodies with thrombosis." *Antiphospholipid syndrome*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=110221&searchterm=antiphospholipid+syndrome (last visited Oct. 2, 2024).

commonly being the product of an autoimmune process. *Id.* at 30 (discussing J.R. Boris et al., *Family History of Associated Disorders in Patients with Postural Tachycardia Syndrome*, 30 Cardiol. Young 388-394 (2020) (filed as pages 44-67 of ECF No. 71)).

Other items of literature offered by Petitioner purport to establish indirect evidence of POTS's autoimmune character, by noting that IVIG[9] treatments (known to ameliorate some autoimmune disease processes) are effective for POTS. Mot. at 30 (discussing J.R. Schofield et al., *Intravenous Immunoglobulin Therapy in Refractory Autoimmune Dysautonomias: A Restrospective Analysis of 38 Patients*, 26 Am. J. Ther. 570-582 (2019) (filed as pages 374-86 of ECF No. 71); B. Rodriguez et al., *Immunomodulatory Treatment in Postural Tachycardia Syndrome: A Case Series*, 28 Eur. J. Neurol. 1692-1697 (2021) (filed as page 372 of ECF No. 71)). But a different, recently-published article has confirmed that in a group of patients with POTS who received IVIG versus a placebo, there was no statistically-significant difference in response. *Id.* (discussing S. Vernino et al., *Randomized Controlled Trials of Intravenous Immunoglobulin for Autoimmune Postural Orthostatic Tachycardia Syndrome (iSTAND)*, 102 J. of Nuerol. 153-163 (2024), filed as Ex. B (ECF No. 75-2) (of the study's 30 participants, 16 received IVIG treatment and 14 received albumin. The participants received eight infusions over the course of twelve weeks. While the IVIG patients had a slightly higher response rate, the difference was not statistically significant.)).

Beyond the foregoing, Respondent argues that Petitioner has not offered sufficient preponderant evidence to prove that the Tdap vaccine can *itself* likely cause POTS (regardless of its autoimmune character). Mot. at 28. Again, Respondent notes that most of Petitioner's literature offered for this proposition has already been rejected in prior decisions, and the new articles are equally unconvincing. *Id.* at 29-30. One article merely discusses *self-reported antecedent events* in a three-month time frame – and does not otherwise conclude that any vaccine can cause POTS. *Id.* at 29 (discussing B. Shaw et al., *The Face of Postural Tachycardia Syndrome – Insights From a Large Cross-Sectional Online Community-Based Survey*, 286 J. of Intern Med. 438-448 (2019) (filed as pages 12-22 of ECF No. 71). Another – TV et al. – discusses patients who were never formally diagnosed with POTS. *Id.* at 30. And the vast majority of Petitioner's evidence involves the HPV rather than Tdap vaccine. *Id.* at 28. The only evidence Petitioner offers to link the Tdap vaccine to POTS is a single case study in which a patient who was diagnosed with a life-threatening *tetanus infection* developed various symptoms that the Petitioner claims are POTS symptoms – severe neck muscle spasms, high blood pressure, sinus tachycardia, fever, and myoclonic leg movement. *Id.* at 32 (referencing Won Seo). That case study thus does not involve the Tdap vaccine, nor does it even mention POTS. *Id.*

[9] "Intravenous Immunoglobulin (IVIG)" is defined as "[a] therap[y] prepared from a pool of immunoglobulins (antibodies) from the plasma of thousands of healthy donors. Immunoglobulins are made by the immune system of healthy people for the purpose of fighting infections…IVIG/SCIG work in different ways to prevent the body from attacking itself and to decrease several types of inflammation in the body." *IVIG*, https://rheumatology.org/patients/intravenous-immunoglobulin-ivig (last visited Oct. 2, 2024).

Finally, Respondent denies that the Tdap vaccine can cause POTS/CFS via molecular mimicry. Mot. at 31. Petitioner's brief merely provided purportedly significant homologies between tetanus toxoid and the Alpha-1 adrenergic receptor, but no corroborative evidence suggesting that these homologies are likely capable of resulting in an immune-mediated form of POTS. *Id.* at 32.[10]

IV. Applicable Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[11] Petitioner does not assert a Table claim, nor does there exist such a claim for POTS (or autonomic disfunction generally) or CFS as the injury – regardless of the vaccine at issue.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not

[10] Furthermore, Respondent argues, Petitioner has failed to provide evidence with respect to the "did cause" causation prong – that the Tdap vaccine caused or significantly aggravated *her* alleged POTS or CFS. Mot. at 33. Thus, no medical provider attributed Petitioner's condition to the Tdap vaccine. *Id.* Instead, Petitioner's complaints were deemed associated with a variety of other causes, including sports injuries, IBS, and anxiety. *Id*. And Petitioner's symptoms did not develop within a medically acceptable timeframe. *Id.* at 34. She first reported unusual fatigue in October 2018, nearly four months after the vaccination, and she did not report symptoms associated with orthostatic change until July 2020. *Id*. Although these arguments all underscore the overall weakness of the claim (and would likely lead to its dismissal even if the "can cause" prong had been satisfied), my focus is on Petitioner's inability to show the Tdap vaccine can cause POTS in the first place, and therefore I do not include determinations specific to these other points in my analysis.

[11] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health and Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." Each *Althen* prong requires a different showing and is discussed in turn along with the parties' arguments and my findings.

Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford,* 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Kalajdzic v. Sec'y of Health & Hum. Servs.*, No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) (arguments "for a less than preponderance standard" deemed "plainly inconsistent with our precedent" (*citing Moberly*, 592 F.3d at 1322)); *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also Howard v. Sec'y of Health & Hum. Servs*., 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *aff'd*, 2024 WL 2873301 (Fed. Cir. June 7, 2024) (unpublished). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

Petitioners may offer a variety of individual items of evidence in support of the first *Althen* prong, and are not obligated to resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). No one

"type" of evidence is required. Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Andreu*, 569 F.3d at 1380. Nevertheless, even though "scientific certainty" is not required to prevail, the individual items of proof offered for the "can cause" prong must *each* reflect or arise from "reputable" or "sound and reliable" medical science. *Boatmon*, 941 F.3d at 1359–60.

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Hum. Servs.*, No. 06–522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356–57 (2011), *aff'd without opinion*, 475 F. App'x. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the

phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11–355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Law Governing Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to

conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face when compared to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility may be required when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the

result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Consideration of Medical Literature*

Both parties filed numerous items of medical and scientific literature in this case, but not every filed item factors into the outcome of this Decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. Appx. 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

D. *Disposition of Case Without Hearing*

I am resolving Petitioner's claim on the filed record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs*., No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

As should be evident from the foregoing, this claim has any number of deficiencies that would make early dismissal appropriate. In particular, it is clear from the record as it stands that Petitioner would unlikely be able to substantiate either claimed injury – she was never formally diagnosed with POTS or CFS,[12] and it does not appear from her medical history that testing

[12] Petitioner's alleged CFS injury was particularly unsupported by the record. The first Vaccine Program case to find a causal link between a vaccine and CFS was *Jane Doe/52 v. Sec'y of Dep't of Health & Hum. Servs*., 2009 WL 5206199 at *16 (Fed. Cl. Spec. Mstr. Dec. 15, 2009), and it provides a good contrast into the kind of presentation that might reflect the existence of CFS. Within three days of receiving the hepatitis B vaccine, the *Jane Doe/52* petitioner

necessary to confirm either was performed.[13] Moreover, the timeframe between when the vaccination occurred and when Petitioner could *arguably* claim either injury manifested was more than a year, and thus facially far too long to be causally related.

Disposition of this claim, however, primarily turns on the first *Althen* prong, which requires a claimant to provide a "persuasive medical theory" demonstrating that the vaccine received can cause or significantly aggravate the type of injury alleged. *Althen*, 418 F.3d at 1278. While a "persuasive medical theory" does not need to meet the standard of medical or scientific *certainty* (and may be supported by a variety of items of circumstantial or indirect proof), it must still be sound and reliable. *Boatmon*, 941 F.3d at 1351.

POTS is a circulation disorder characterized by a group of symptoms (not including hypotension) that sometimes occur when a person assumes an upright position, including tachycardia, tremulousness, lightheadedness, sweating, and hyperventilation. The condition is seen more often in women than in men, and its etiology is uncertain. "Postural orthostatic tachycardia syndrome," *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com /dorland/definition?id=111236 (last visited Sep. 25, 2024).

As I have concluded in numerous prior cases, POTS is most commonly *not* attributable to an autoimmune process. *See e.g.*, *C.F.*, 2023 WL 2198809, at *32; *E.S. v. Sec'y of Health & Hum. Servs.*, No. 17-480V, 2020 WL 9076620, at *43 (Fed. Cl. Spec. Mstr. Nov. 13, 2020), *mot. for review den'd*, 154 Fed. Cl. 149 (2021). Rather, POTS usually results from "deconditioning" (physical changes in the body caused by physical inactivity and/or an extremely sedentary lifestyle), hypovolemia (inadequate intake of fluids), or cardiac atrophy (a condition that occurs when the heart muscles waste away). *C.F.*, 2023 WL 2198809, at *30. While some evidence has emerged in recent years that a small subset of POTS cases might have an autoimmune basis, this is the exception to the rule. *E.S.*, 2020 WL 9076620, at *43. And the independent medical or scientific evidence that would support the possibility of an autoimmune version of the condition is scant and incomplete – and certainly does not point to vaccination as a triggering factor. *Id.*

developed flu-like symptoms, malaise, low back pain, sore throat, lymph node swelling, musculoskeletal pain, and extreme exhaustion – she was eventually bedridden. *Id.* at *2. These symptoms lasted for two years before the petitioner was ultimately diagnosed with chronic fatigue syndrome. *Id.* But the symptoms Petitioner complains of that might arguably reflect CFS involved sporadic reports of intermittent, transient fatigue. Mot. at 27. Otherwise, the record only includes medical chart code references to CFS (Opp. at 37), and that diagnosis is not set forth as a treater conclusion, based on clinical presentation or test results.

[13] In previous cases, for example, I have noted that the tilt table test (in which an individual's orthostatic readings are continuously taken while the subject is secured to a flat tale that is then titled up), is the "gold standard" for diagnosing POTS. *See Yalacki v. Sec'y of Health & Hum. Servs.*, No. 14-278V, 2019 WL 1061429 at *5, *35 (Fed. Cl. Jan. 31, 2019), *mot. for review den'd*, 146 Fed. Cl. 80 (2019). Petitioner's health care providers never ordered a tilt table test for her.

Petitioner, however, insists that POTS is predominantly an autoimmune disease that can be triggered by vaccination. Brief at 5. To prove this theory, Petitioner relies heavily on arguments involving the HPV vaccine. *Id.* But I have repeatedly found such arguments unpersuasive – and I have reached this conclusion after hearings, as well as evaluation of large amounts of relevant independent medical and scientific literature. *See, e.g.*, *C.F.*, 2023 WL 2198809, at *36 (there is not preponderant evidence of a reliable medical theory causally connecting Petitioner's HPV vaccine to her POTS); *Hughes v. Sec'y of Health & Hum. Servs.*, No. 16-930V, 2021 WL 839092, at *30 (Fed. Cl. Spec. Mast. Jan. 4, 2021) (finding that Petitioner was unable to preponderantly demonstrate that the HPV vaccine can cause POTS); *Otto v. Sec'y of Health & Hum. Servs.*, No. 16-1144, 2020 WL 4719285, at *2 (Fed. Cl. Spec. Mstr. June 17, 2020) (finding Petitioner's causation theory – that the HPV vaccine can cause POTS – unreliable and unsupported by sufficient scientific/medical evidence); *E.S.*, 2020 WL 9076620, at *42 (ruling that Petitioner has not established that the HPV vaccine or flu vaccine can cause POTS). And my conclusion does not reflect merely my own view on the subject – for *no* special masters have ever found POTS is caused by the HPV vaccine. *Kelly v. Sec'y of Health & Hum. Servs.*, No. 21-827V, 2024 WL 3498199, at *9 (Fed. Cl. Spec. Mstr. June 26, 2024).

Petitioner nevertheless relies heavily on this discredited association between POTS and the HPV vaccine – and to do so, she offers an abundance of literature that I have previously rejected as unreliable or unpersuasive. *See e.g.*, *C.F.*, 2023 WL 2198809, at *15, *17-19, *32 (discussing Blitshteyn, Chandler, Schofield, and Brinth). Accordingly, she makes as a centerpiece of her causation argument in this case a contention that *itself is insufficiently preponderant* – and one that numerous prior cases directly address. Because of this – and given the obvious point that the HPV vaccine is not at issue in any event – these arguments do nothing to advance Petitioner's position.

This leaves open (if barely) the possibility that the Tdap vaccine could be shown to be causal of POTS in a way the HPV vaccine has not been in past matters. But (and despite due opportunity herein, via the briefing of this matter) the only evidence offered specific to the relevant vaccine is a single case study, in which a patient with a life-threatening tetanus infection developed POTS-like symptoms (Won Seo). Brief at 17-18. Won Seo says nothing about the Tdap vaccine, and did not involve a POTS diagnosis either. None of the other filed materials involve either the Tdap vaccine or its constituent wild analogs.

To compensate for the fact that no medical literature preponderantly supports her causal theory, Petitioner invokes the general theory of molecular mimicry. Brief at 20. She argues that there is significant homology between peptide components of the Tdap vaccine and Alpha-1 adrenergic receptor, allowing for the possibility that an antibody-driven cross-reaction could occur and ultimately cause POTS. *Id.* But I have consistently held that establishing homology is not enough to prove that molecular mimicry constitutes a likely mediating mechanism for a vaccine-triggered injury. *See Sullivan v. Sec'y of Health & Hum. Servs.*, No. 10-398V, 2015 WL 1404957,

at *17-18, n. 30 (Fed. Cl. Spec. Mstr. Feb. 13, 2015) (while the law does not require Petitioner to "prove" homology in a Program case, mere assertion that HPV strain shares sequences with human body such that molecular mimicry might occur resulting in injury was by itself insufficient to satisfy burden); *see also Yalacki v. Sec'y of Health & Hum. Servs.*, No. 14-278V, 2019 WL 1061429, at *34 (Fed. Cl. Spec. Mstr. Jan. 31, 2019), *mot. for review den'd*, 146 Fed. Cl. 80 (2019) (commenting on petitioner's theory that the Hep B vaccine could trigger a pathogenic process resulting in an autoimmune attack, but finding that it was "not enough for a claimant to invoke the concept of molecular mimicry" as petitioner needed to "cite to evidence, circumstantial or otherwise, suggesting reason to find it plausible that the proposed autoimmune cross-reaction triggered by the relevant vaccine does occur").

Put simply, the fact that molecular mimicry has been deemed applicable to *some* autoimmune diseases, or has scientific reliability as a mechanism in certain circumstances, does not mean the mechanism is applicable across the board to any vaccine injury claim. *McKown v. Sec'y of Health & Hum. Servs.*, No. 15-1451V, 2019 WL 4072113, at *50 (Fed. Cl. Spec. Mstr. July 15, 2019) ("merely chanting the magic words 'moleculary mimicry' in a Vaccine Act case does not render a causation theory scientifically reliable, absent additional evidence specifically tying the mechanism to the injury and/or vaccine in question."); *see also Deshler v. Sec'y of Health & Hum. Servs.*, No. 16-1070V, 2020 WL 4593162, at *20 (Fed. Cl. Spec. Mstr. July 1, 2020) ("though molecular mimicry is a generally accepted scientific principle, mere invocation of the scientific term does not carry a petitioner's burden in a Program case.").

Thus, there is insufficient evidence offered herein connecting the Tdap vaccine to POTS – *even less* than what is offered to connect the HPV vaccine to POTS (but which has been repeatedly rejected in prior well-reasoned decisions). And nothing new has been identified from the medical or scientific community that would provide a basis for allowing this claim to continue.

The same is true for any putative association between CFS and the Tdap vaccine. As noted, it is not evident that Petitioner ever *had* CFS. And even if she had properly received such a diagnosis, and the record supported it, claimants in the Vaccine Program have been routinely unsuccessful in arguing that vaccines can cause CFS. *See e.g.*, *Skinner-Smith v. Sec'y of Health & Hum. Servs.*, No. 14-1212V, 2022 WL 4116896 (Fed. Cl. Spec. Mstr. Aug. 15, 2022), *reconsideration denied*, 2022 WL 13461862 (Fed. Cl. Spec. Mstr. Sept. 9, 2022) (nothing in the record to support the conclusion that the Tdap vaccine can cause immune dysregulation leading to CFS); *Johnson v. Sec. of Health & Human Servs.*, No. 14-254V, 2018 WL 2051760 (Fed. Cl. Spec. Mstr. Mar. 23, 2018) (denying entitlement in case alleging CFS and POTS caused by HPV vaccination); *D'Angiolini v. Sec'y of Health & Hum. Servs.*, No. 99-5788V, 2014 WL 1678145 (Fed. Cl. Spec. Mstr. March 27, 2014) (denying entitlement for adverse reaction, including CFS,

allegedly caused by hepatitis B vaccine).[14] These decisions do not control the disposition of this case, but they underscore why (and in the absence of some independent basis for reevaluation) rejection of this causal theory would be reasonable.

My determination to dismiss the case comes relatively early in the matter's existence, and before substantial expert input was sought, but is a reasonable outcome in light of the claim's very-evident deficiencies. Special masters are empowered to decide what discovery is needed to resolve a given matter. 42 U.S.C. § 300aa–12(d)(3)(B); *see also Felix v. Sec'y of Health & Hum. Servs.*, 172 Fed. Cl. 626, 632 (2024) ("[n]ot all vaccine cases merit expert witness testimony"). They also have "wide discretion in determining whether to conduct an evidentiary hearing." *Kreizenbeck.*, 945 F.3d at 1365; *see also Oliver v. Sec'y of Health & Hum. Servs.*, 900 F.3d 1357, 1364 n.6 (Fed. Cir. 2018) (holding that "Chief Special Master acted within her discretion in denying" the petitioner's request for a hearing). What matters at bottom is whether a claimant has been afforded "a full and fair opportunity to present [their] case and creat[e] a record sufficient to allow review of the special master's decision" through medical evidence and proffered affidavits in accordance with Vaccine Rule 3(b)(2). *See, e.g., K.A. v. Sec'y of Health & Hum. Servs.*, 164 Fed. Cl. 98, 115–19 (2022) (decision to deny requests to retain and present particular expert witness did not deprive the parties of "a full and fair opportunity to present his case" or otherwise amount to an abuse of discretion), *aff'd*, No. 23-1315, 2024 WL 2012526 (Fed. Cir. May 7, 2024) (per curiam) (table).

Relying on my extensive experience with POTS cases, I noted a glaring problem with this claim early on in its existence, and one that I expected would render the claim untenable. But before I dismissed the matter, I invited the Petitioner to attempt to address my concerns – in particular by offering whatever independent evidence she could that would suggest this claim would fare better than similar prior matters, and thus should be allowed to progress. In reaction, Petitioner filed extensive medical records and briefs to support her claim, along with a lengthy appendix of medical and scientific articles. Yet this effort amounted to repeating what has been rejected in numerous prior Program matters regarding the HPV vaccine and POTS. And she otherwise has offered scant evidence specific to the Tdap vaccine, despite *ample opportunity to do so*. Under such circumstances, it cannot be said that Petitioner has been deprived of a chance to prove a claim that is so self-evidently unlikely to succeed.

[14] At best, a special master in one case found that the petitioner preponderantly established the *influenza vaccine* as a cause of chronic fatigue syndrome. *Bryan v. Sec'y of Health & Hum. Servs.*, No. 14-898V, 2020 WL 7089841 at *1 (Fed. Cl. Spec. Mstr. Oct. 9, 2020). But *Skinner-Smith* noted that what was arguably true of the flu vaccine has not been shown to be applicable to the Tdap vaccine. *Skinner-Smith*, 2022 WL 4116896., at *35.

CONCLUSION

Petitioner cannot substantiate her claim that the Tdap vaccine can cause POTS or CFS. I therefore must DENY entitlement in this case.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[15]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[15] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.